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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,612	06/03/2002	Corinne Elizabeth Augelli-Szafran	5944-01-DRK	3747

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EXAMINER	
BERNHARDT, EMILY B	

ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 08/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/009,612	AUGELLI-SZAFRAN ET AL.	
	Examiner	Art Unit	
	Emily Bernhardt	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *10-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 22-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/7/01*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicant's election of I and in particular the species of eg.26 in the reply filed on 5/26/04 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Method claims 4-9 will be examined. Nonelected claims 10-21 employ labelled compounds and thus do not correspond in scope with products claimed in I.

Claims 1,4,6-9 and 22-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. "Substituted" in the claims is unclear as to intended scope. While specification describes some intended groups the definition is open-ended in view of the wording "for example" and "preferably" stated on p.11-12. A similar issue was present in Ex parte Remark 15 USPQ 2d 1498 (at p.1500) in which it was decided that claim language that relied on open-ended language was "vague and uncertain" since it was not clear what else was intended to be covered.

2. In claims 6, 9 and 24 "compound of claim 4" is recited but 4 is a method claim.

3. Claims 7-9 are of indeterminate scope for more than one reason. How does one determine who is in need and who is not of inhibiting the aggregation of amyloid proteins? One may have no visible symptoms and still be in need. It may turn out

with further research that everyone is in need. What cutoff point determines successful inhibitory activity? Specification provides no guidance. There is no art-recognized disorder known as "inhibiting the aggregation of amyloid proteins". Defining a disease(s) by its (their) underlying cause renders the scope of intended uses indeterminate since the claim language may read on diseases not yet known to be caused by or affected by such action or in ways not yet understood. Additionally, determining whether a given disease responds or not to such a mode of action involves much experimentation since a negative response from one patient does not mean the drug isnt useful as no drug has 100% effectiveness. Thus what "success rate" determines if a particular inhibitor is effective and how many patients (and dosage regimens) need to be tested? The test for determining compliance with 35 USC 112, par.two is whether applicants have clearly defined "their" invention not what may be discovered by future research as this type of claim language clearly requires.

Claims 7-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating Alzheimer's Disease as recited in claims 4-6, does not reasonably provide enablement for the diseases listed in the specification on p.1, which are collectively known as prion diseases. The specification does not enable any person skilled in the art to which it pertains, or

with which it is most nearly connected, to use the invention commensurate in scope with these claims. The notion that simply having the ability to inhibit the aggregation of beta amyloid peptide will enable the treatment of such disorders has not been substantiated in the art. Note Barret provided with this action . The article describes for one compound having undergone more testing than described herein as a possible treatment for Creutzfeldt-Jakob disease the disappointing results. On p.8468 in the DISCUSSION section it is stated: "To date, there is no effective therapy for prion diseases. Thus the level of skill in the treatment of these diseases is low not high and as such claiming such uses is not warranted based on the evidence of record.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Uryu (US'369). Uryu describes a compound within the instant scope. See di-Et amino species in col.7, line 45 which is made by the same process that applicants employ.

Claims 1 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Tadao (EP'109). The EP publication provided by applicants describes a compound within the instant scope for treating diabetes. See compound 14 on p.18.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2-3 and 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tadao. The teachings of Tadao as discussed above are incorporated herein. Compounds embraced by the claims rejected herein are higher homologs of Tadao's compound 14. Such compounds are expressly taught as can be seen in the definition for R2 which includes dialkyl amino of C1-C4 carbon atoms. Thus it would have been obvious to one skilled in the art at the time the instant invention was made to replace the methyl groups in the exemplified compound with ethyl, propyl, butyl,etc. and in so doing obtain additional compounds for use as aldose reductase inhibitors in view of the equivalency teaching outlined above.

Claima 1-9 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bue-Valesky (US'314). The US patent was cited in applicants'

IDS. It describes similar compounds to that claimed herein for treating Alzheimer's Disease (AD) based on inhibitory activity toward beta amyloid deposits as discussed in col.35. Closest compounds, namely examples 82 and 86 differ in only one respect from that claimed herein. For eg.82 the difference is at the 3-position of the thiazole ring- H vs instant acetic acid and for eg.86 the difference is in the nature of substituent on phenyl ring indirectly attached at the 5-position- 3-methanesulfonamido vs. instant bisalkylamino. Note that the patent teaches the interchangeability of the aforementioned groups. See especially definition of R7 which includes higher alkylaminos as well as dimethylamino exemplified by eg.82. Also see the claims such as 2-7 which expressly include applicants' compounds. Thus it would have been obvious to one skilled in the art at the time the instant invention was made to modify the closest compounds pointed out above by incorporating the acetic acid group at the 3-position and include the bisalkylamino group on the phenyl ring and in so doing obtain additional compounds for use in treating AD and other uses taught by the applied art in view of the equivalency teachings outlined above.

The data depicted on p.3 of the specification has been noted. It includes some of the examples in US'814. However it is not persuasive of a patentable distinction given there are no side-by-side showing with closest instant

compounds and egs. 82 and 86. Additionally, a value of >100 uM appears to be acceptable in establishing activity as reported by applicants for instant compounds on p.40-42. Note Ex parte Gelles 22 USPQ 2d 1318 especially p.1319.

Claim(s) to the elected species (compound, composition and use for treating AD) would be allowable over the art of record.

Commonly assigned WO'988 is also made of record. While it discloses similar or identical compounds it is not a competent reference. Corresponding US case, serial no. 10/009637, does not claim alkanoic acid derivatives at the 3-position.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Bernhardt whose telephone number is (571) 272-0664.

If attempts to reach the examiner by phone are unsuccessful, the supervisor for AU 1624, Dr. Mukund Shah, can be reached at (571)272-0674.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

E Bernhardt

EMILY BERNHARDT

PRIMARY EXAMINER

Group 1600